SECTION I – 510(K) Summary

K062528

FOI Releasable

JAN 26 2007

Pursuant to § 513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Suros Surgical Systems, Inc. is required to submit with this premarket notification "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Suros Surgical Systems, Inc. chooses to submit a summary of information respecting safety and effectiveness.

Classification Name:	Marker, Radiographic Implantable
Common/Usual Name:	Tissue Site Marking System
Proprietary Name:	None at this time
Device Classification:	Class II

Description	Number	21 CFR Ref.
Implantable Clip	NEU	§ 878.4300

Owner/Operator: Suros Surgical Systems, Inc. – FDA Registration # 3003862400
Northwest Technology Center
6100 Technology Center Drive
Indianapolis, IN 46278
317-344-7500

Contact: Heidi Strunk
Director, Quality & Regulatory
Suros Surgical Systems, Inc.
Northwest Technology Center
6100 Technology Center Drive
Indianapolis, IN 46278
317-344-7500

DESCRIPTION OF DEVICE

The Tissue Site Marking System is supplied as a sterile device and is intended for single patient use only. The Tissue Site Marking System is composed of two elements:

1) an implantable device (marker) including a bioabsorable component and a permanent component and

SECTION I – 510(K) Summary

2) a deployment device.

The Tissue Site Marking System is intended for use with the manual method of deployment under the following imaging modalities: ultrasound, x-ray, magnetic resonance, nuclear, computed tomography, and direct visualization.

INDICATIONS FOR USE

The Tissue Site Marking System is indicated for the permanent radiographic marking of sites in soft tissue.

CONTRAINDICATIONS

None known

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Heidi H. Strunk
Director, Quality and Regulatory
Suros Surgical Systems. Inc.
6100 Technology Center Drive
INDIANAPOLIS IN 46278

JAN 26 2007

Re: K062528
Trade/Device Name: Tissue Site Marking System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: December 22, 2006
Received: December 26, 2006

Dear Ms. Strunk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K062528

Device Name: Tissue Site Marking System

Indications for Use: The Tissue Site Marking System is indicated for the permanent radiographic marking of sites in soft tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062528

Prescription Use: V
(Per 21 CFE 801.109)

OR

Over-the Counter Use: _____

(Optional Format 1-2-96)